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APPLICATION NO.	F	ILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/673,859	10/673,859 09/29/2003		Laurence J. Cull	P03195	1368
23702	7590	06/13/2006		EXAMINER	
Bausch & I		-	FRANTZ, JESSICA L		
One Bausch Rochester,				ART UNIT	PAPER NUMBER
,				3746	

DATE MAILED: 06/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application	n No.	Applicant(s)	_			
		10/673,85	9	CULL ET AL.				
	Office Action Summary	Examiner		Art Unit	_			
	·	Jessica L.	Frantz	3746				
Period fo	The MAILING DATE of this communicati or Reply	ion appears on the	cover sheet with the c	orrespondence address				
A SH WHIC - Exter after - If NO - Failu Any r	ORTENED STATUTORY PERIOD FOR CHEVER IS LONGER, FROM THE MAILING IS IN 1975 IN	ING DATE OF TH CFR 1.136(a). In no evention. y period will apply and will by statute, cause the appl	IS COMMUNICATION ont, however, may a reply be timed texpire SIX (6) MONTHS from the ication to become ABANDONEI	I.  lely filed  the mailing date of this communication.  O (35 U.S.C. § 133).				
Status								
<ol> <li>Responsive to communication(s) filed on <u>29 September 2003</u>.</li> <li>This action is <b>FINAL</b>. 2b)  This action is non-final.</li> <li>Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11, 453 O.G. 213.</li> </ol>								
Dispositi	on of Claims							
5)□ 6)⊠ 7)□ 8)□	Claim(s) 1-10 is/are pending in the appli 4a) Of the above claim(s) is/are w Claim(s) is/are allowed. Claim(s) 1-10 is/are rejected. Claim(s) is/are objected to. Claim(s) are subject to restriction on Papers	rithdrawn from cor						
10)⊠	The specification is objected to by the Ex The drawing(s) filed on 9/29/2003 is/are: Applicant may not request that any objection Replacement drawing sheet(s) including the The oath or declaration is objected to by	a) accepted o to the drawing(s) b correction is require	e held in abeyance. See ed if the drawing(s) is obj	e 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).				
Priority u	inder 35 U.S.C. § 119							
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>								
2) Notice	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-9 nation Disclosure Statement(s) (PTO-1449 or PTO r No(s)/Mail Date		4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal Pa 6) Other:					

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#### **DETAILED ACTION**

#### Information Disclosure Statement

1. The Information Disclosure Statements (IDS) submitted on 2/22/2005 and 9/29/2003 are acknowledged. The references listed therein have been considered.

## Specification

- 2. The disclosure is objected to because of the following informalities:
  - The reference numeral 84 is described as the "other end" of pump loop 50 in the second sentence of paragraph 0033 and later described as "tube holders" in the sixth sentence of paragraph 0033.
  - The last sentence of paragraph 0027 should read "Of course, this is not a concern if as is known, a pinch valve operates to close the aspiration line during venting.

Appropriate correction is required.

#### Claim Objections

3. Claim 1 is objected to because of the following informalities: On the last line of the claim, the word "place" is misspelled and should be corrected to read "plate."

Appropriate correction is required.

# Claim Rejections - 35 USC § 112

4. Claims 2, 4, 6 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear to use the word "held" or

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"holding" to describe the length of time the invention is to be "vented" and considering the position is not physically held in place.

For claim interpretation purposes, in the broadest reasonable interpretation of the invention, in stating that the vent position is "held" for less than one second, it could be understood that the pump head is moved away from the backing plate quickly and then reassembled back into place. Alternatively, it could be understood that the pump head is moved away from the backing plate in less than one second and then anytime after this one second range the pump is in an "off" position and that the pump head is left in the disengaged position.

### Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 6. Claims 1-4, and 9-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Aubert U.S. Patent # 5,249,937. Aubert discloses a peristaltic pump comprising: a housing (36, 38, 40); a pump head (22) having a plurality of rollers (26a); a backing plate (34) attached to the housing; the pump head for causing the rollers to rotate about a central axis of the pump head, such that the rollers and backing plate cooperate to pinch a length of surgical tubing (28) and peristaltically pump fluids from a surgical site to a collection bag (30); and wherein at least one of the pump head and backing plate is moveable from a tubing pinched position to a tubing vent position

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during use of the pump, such that the tubing is vented by removing the pinch between the rollers and the backing place. (Please refer to Figure 4 to observe how the pump head is able to be removed from the backing plate to cause venting.)

Furthermore, it is inherently capable to remove the pump head from the backing plate for a short period of time allowing the apparatus to be in the tubing vent position which is held for less than 1 second.

Aubert further discloses that as the pump head rotates, aspirant (not labeled, disclosed as "liquid") is peristaltically pumped through the tubing; and wherein the pump head is moveable during operation of the pump from a tubing engaged position to a tubing vent position, such that the tubing is vented by the movement of the pump head. Again, it is inherently capable to remove the pump head from the backing plate for a short period of time allowing the apparatus to be in the tubing vent position for less than 1 second.

Aubert also discloses that the pinch in the tubing is capable of being removed during operation of the pump. (Please refer to Figure 4). When the pinch is removed, the tubing is vented. And again, it is inherently capable to remove the pinch for less than 1 second.

7. Claims 1, 5, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Leveen U.S. Patent # 4,813,855. Leveen discloses peristaltic pump comprising a housing (9) including a backing plate (concave inner surface of shoe 19) attached to the housing; and rotating a plurality of rollers (16) about a central axis of a pump head (17) held within the housing. Referring to claim 1, Leveen further discloses that the

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rollers and the backing plate cooperate to pinch a length of surgical tubing (34) and peristaltically pump fluids (Column 3, lines 25-31). The phrase "from a surgical site to a collection bag" is not positively claimed, and the invention of Leveen is inherently capable of performing in this manner. Furthermore, Leveen discloses that at least one of the pump head and the backing plate are moveable from a tubing pinched position to a tubing vent position during the use of the pump, such that the tubing is vented by removing the pinch between the rollers and the backing plate. (Column 3, lines 40-43 and Column 4, lines 21-28). It is inherent that if the pinch is no longer present, the tube is vented. Referring to claim 5, Leveen further discloses pinching a length of tubing (34) between the rollers and the backing plate to peristaltically pump aspirant (therapeutic agents in liquid form, column 1, lines 10-11) through the tubing; and moving one of the pump head and the backing plate from a tubing pinched position to a tubing vent position, such that the tubing is vented by removing the pinch between the rollers and the backing plate. (Column 3, lines 40-43 as well as Figures 2, 3 and 4). Again, it is inherent that if the pinch is removed, the tube is vented. The method for providing the above stated device is inherent given the teachings of the pumping apparatus disclosed by Leveen et al. Referring to claim 9, Leveen discloses a length of surgical tubing (34) for engaging the rollers, such that as the pump head rotates, aspirant (therapeutic agents in liquid form, column 1, lines 10-11) is peristaltically pumped through the tubing by the rollers pinching closed a section of tubing (Column 3, lines 25-31 and 40-43) and wherein the pinch closing a section of tubing is removed during operation of the pump such that the tubing is vented by the removal of the pinch

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(Column 3, lines 40-43 and Column 4, lines 21-28). It is again inherent that if the pinch is removed, the tube is vented.

Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Ognier 8. U.S. Patent # 6.062,829. Ognier discloses peristaltic pump comprising a housing (as shown in Figure 5) including a backing plate (recess 5 of stator 2) attached to the housing; and rotating a plurality of rollers (6) about a central axis (4) of a pump head (3) held within the housing. Referring to claim 1, Ognier further discloses that the rollers and the backing plate cooperate to pinch a length of surgical tubing (1) and peristaltically pump fluids. The phrase "from a surgical site to a collection bag" is not positively claimed, and the invention of Ognier is inherently capable of performing in this manner. Furthermore, Ognier discloses that at least one of the pump head and the backing plate are moveable from a tubing pinched position to a tubing vent position during the use of the pump, such that the tubing is vented by removing the pinch between the rollers and the backing plate. (Column 3, lines 39-41). Referring to claim 2, the disclosed apparatus of Ognier is inherently capable of removing the pump head from the backing plate for a short period of time allowing the apparatus to be in the tubing vent position for less than 1 second. (Column 3, lines 39-41 and Column 4, lines 54-59). Referring to claim 3, Ognier discloses a length of surgical tubing (1) for engaging the rollers, such that as the pump head rotates, aspirant is peristaltically pumped through the tubing (Abstract and Column 1, lines 13-16) and wherein the pump head is moveable during the operation from a tubing engaged position to a tubing vent position such that the tubing is vented by the movement of the pump head

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(Column 4, lines 54-59). Referring to claim 4, the disclosed apparatus of Ognier is inherently capable of removing the pump head from the backing plate for a short period of time allowing the apparatus to be in the tubing vent position for less than 1 second. (Column 3, lines 39-41 and Column 4, lines 54-59). Referring the claim 5, Ognier discloses pinching a length of tubing (1) between the rollers and the backing plate to peristaltically pump aspirant (Abstract and Column 1, lines 13-16) through the tubing; and moving one of the pump head and the backing plate (Column 3, line 39-41) from a tubing pinched position to a tubing vent position, such that the tubing is vented by removing the pinch between the rollers and the backing plate. The method of providing the above stated device is inherent given the teachings of the pumping apparatus disclosed by Ognier. Referring to claim 6, Ognier discloses that the pump head can be completely disengaged from the backing plate in the event of an uncontrolled overpressure. Furthermore, Ognier states the desire for rapid disengagement. (Column3, lines 39-41 and Column 4, lines 54-59). It is inherent that rapid is less than one second. Furthermore, in reference to claim 7, Ognier discloses engaging a length of surgical tubing (1), such that as the pump head rotates the rollers aspirant is peristaltically pumped through the tubing; and translating the pump head while the rollers are rotating from a tubing engaged position to a tubing vent position, such that the tubing is vented by the translation of the pump head. (Column 4, lines 54-59). Referring to claim 8, Ognier discloses that the pump head can be completely disengaged from the backing plate in the event of an uncontrolled overpressure. Furthermore, Ognier states the desire for rapid disengagement. (Column3, lines 39-41

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and Column 4, lines 54-59). It is inherent that rapid is less than one second. In reference to claim 9, Ognier discloses a length of surgical tubing (1) for engaging the rollers, such that as the pump head rotates, aspirant is peristaltically pumped through the tubing by the rollers pinching closed a section of the tubing (Abstract and Column 1, lines 13-16) and wherein the pinch closing a section of tubing is removed during operation of the pump, such that the tubing is vented by the removal of the pinch (Column 4, lines 54-59). Referring to claim 10, the disclosed apparatus of Ognier is inherently capable of removing the pump head from the backing plate for a short period of time allowing the apparatus to be in the tubing vent position for less than 1 second. (Column 3, lines 39-41 and Column 4, lines 54-59).

## Claim Rejections - 35 USC § 103

- 9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 10. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ognier U.S. Patent # 6,062,829. Ognier teaches the invention as claimed and is inherently capable of venting for less than one second as stated above. However, to obviate any doubt, Ognier discloses the ability for rapid disengagement of the pump head in the radial direction away from the backing plate in case of an uncontrollable

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overpressure. (Column 3, lines 43-46) As for the claimed range of less than one second, it has been held that finding the workable ranges in the art is within the ordinary skill in the art. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to employ the claimed range as an obvious matter of finding the workable ranges in the art.

11. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ognier U.S. Patent # 6,062,829, as applied above, in view of Aubert U.S. Patent # 5,249,937. Ognier teaches the invention as claimed and is inherently capable of venting for less than one second. However, referring claim 1 of the application at hand, the phrase "pump fluids from a surgical site to a collection bag" is not positively claimed as discussed above. The invention of Ognier does not specifically recite a collection bag but is inherently capable of pumping fluids from a surgical site to a collection bag. However, to obviate any doubt, the invention of Ognier may be modified with the invention of Aubert who is discussed above and includes a collection bag (30) for the purpose of storing a liquid substance. (Abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided Ogneir's device with a collection bag as taught by Aubert in order to store a liquid substance.

#### Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following references substantially describe the invention as claimed:

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- Soderquist et al. (5,082,429)
- Azzolini (4,043,712)
- Haser et al. (Patent Application Publication # 2004/0037724)
- Clemens (4,025,241)
- Rauh (5,693,020)
- Soderquist (4,886,431)
- Mondier (6,406,267)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica L. Frantz whose telephone number is 571-272-5822. The examiner can normally be reached on Monday through Friday 8:30a.m.-5:00p.m. E.S.T..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Thorpe can be reached on (571) 272-4444. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

J.F.

JF

PRIMARY EXAMINER

TAE JUN KIM
PRIMARY EXAMINER